Washington State Health Care Authority

Report to the Legislature

Complex treatment needs of persons with opioid use disorder

Substitute Senate Bill 5380; Section 28(6)(b); Chapter 314; Laws of 2019

December 28, 2021

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Executive summary

In 2019, the Washington State Legislature passed Substitute Senate Bill (SSB) 5380, which required the Washington State Health Care Authority (HCA) to:

> Work with stakeholders to develop a set of recommendations to the governor and the legislature that:
>
> (i) Propose, in addition to those required by federal law, a standard set of services needed to support the complex treatment needs of persons with opioid use disorder treated in opioid treatment programs;
> (ii) Outline the components of and strategies needed to develop opioid treatment program centers of excellence that provide fully integrated care for persons with opioid use disorder;
> (iii) Estimate the costs needed to support these models and recommendations for funding strategies that must be included in the report;
> (iv) Outline strategies to increase the number of waivered health care providers approved for prescribing buprenorphine by the substance abuse and mental health services administration; and
> (v) Outline strategies to lower the cost of federal food and drug administration approved products for the treatment of opioid use disorder.

This report provides background information on the opioid crisis in Washington, and describes the structure, function, and current capacity of opioid treatment programs (OTPs) in Washington. The background is followed by responses to the legislative requests above. To summarize, HCA proposes the following strategies to improve the quality of care delivered in OTPs and to better support their role in the response to the ongoing opioid epidemic.

- Implement the 15 standards developed in conjunction with the Centers for Medicare and Medicaid Services (CMS), to improve the consistency of care delivered across the OTPs;
- Increase funding to turn all OTP programs into level 1 centers of excellence, through development of infrastructure, increases in staffing, and development of data systems capable of tracking referrals and patient outcomes;
- Work with OTPs to implement the Medicare billing structure to effectuate detailed reporting on the number and type of services being performed in OTPs, ensuring calculation of the service rate more accurately reflects the number and type of services being performed;
- Monitor the effects of recent federal rule changes on the number of waivered providers treating persons covered by Medicaid with medications for opioid use disorder (OUD); and
- Continue to support state and federal drug price transparency efforts and federal price control regulations that may assist in effectively lowering the cost of methadone and buprenorphine.

Background

Overdose deaths in Washington

Washington State is experiencing a fentanyl-driven overdose crisis. Current trends shown on the Washington State Department of Health (DOH) Opioid Overdose website suggest the total number of overdoses will be the highest recorded. Fortunately, there are effective medications for the treatment of OUD. While two of the three Food and Drug Administration (FDA)-approved medications can be prescribed in a primary care office, OTP behavioral health agencies are the only outpatient treatment setting where federal law permits the use of all FDA-approved medications for the treatment of OUD: methadone-, buprenorphine-, and naltrexone-containing products.

Since their inception in the 1960's, methadone was the only drug able to be prescribed in OTPs. It is biologically described as a "full agonist", meaning it completely binds to and fully activates opioid receptors in the body. It is the most potent FDA-approved medication allowed for the treatment of OUD. It can only be dispensed for the treatment of OUD in an outpatient OTP or "methadone clinic". Buprenorphine, which can be prescribed outside of OTPs, also occupies the opioid receptor, but it is not as potent as methadone. This is an important distinction to highlight. Buprenorphine was developed to treat OUD, when heroin and prescription opioids were the primary substances being used by people with OUD. Because fentanyl is a much more potent opioid than heroin or oxycodone, many people using fentanyl require methadone medication to treat their OUD, increasing the need for services provided in OTPs.

Services currently provided in OTPs

An OTP is one form of a substance use disorder (SUD) treatment agency. They are licensed by both the state and federal governments and registered with the federal Drug Enforcement Agency (DEA). A patient who receives care at an OTP is administered medication and receives take-home doses of medication directly from a dispensary at the OTP. Persons with OUD can only access methadone treatment in an OTP.

Care provided at OTPs is limited in scope. With the passage of SSB 5380 (2019), programs are required to offer all FDA-approved medications for OUD. Federal requirements include the provision of drug tests, offering testing for infections associated with injection drug use, initial and periodic medical visits, and a limited amount of SUD counseling.

To provide this array of services, OTPs have multidisciplinary treatment teams that include:

- Prescribing practitioners (i.e., medical doctors, doctors of osteopathy, advanced registered nurse practitioners, physician assistants);
- Nurses (i.e., licensed practical nurses and registered nurses); and
- Counselors (SUD professionals)

This is in contrast to other SUD programs, which are generally staffed only by SUD professionals (SUDPs) and support staff. This array of services makes the costs of operating an OTP much higher than other SUD agencies.

Current capacity

As of November 1, 2021, there were 31 OTPs in Washington State, each serving between 200 to more than 1,000 patients. There is no federal rule limiting the number of individuals an OTP can serve in a

community, but state law in RCW 71.24.590(2) does allow counties to set patient census limits (i.e., maximum capacity for a program).

Four of the 31 OTPs are owned and operated by Washington State Tribes (i.e., Lummi, Muckleshoot, Stillaguamish, and Swinomish). See HCA's Opioid Treatment Programs Directory.

OTPs in Washington State collectively serve more than 14,000 people with a primary OUD diagnosis. Using information from the HCA Opioid Use Disorder Treatment for Medicaid Population dashboard, 15% of people with Medicaid being treated for OUD are receiving care in OTPs. Access to methadone is not equal across the state. Few programs exist in central and eastern Washington.

Complex needs of patients with an OUD

OTPs were initially established and funded to treat people with OUD using methadone, as it was the only FDA-approved drug available. Over time, other medications have been developed for the treatment of opioid, alcohol, and tobacco use disorders. Other SUDs, in particular methamphetamine and cocaine use disorders, do not have medications that work. Treatment for these disorders require counseling or other behavioral interventions. In addition, the concurrent use of multiple illicit substances was not as common in the 1960's as it is today, so there was not much need to treat multiple substances at once. OTPs are not funded to provide any of the newly developed medications used to treat SUDs or any of these additional behavioral treatments.

One of the hallmarks of SUDs is the person's inability to control their use, even when the impacts to their physical and mental health are severe. This is a biologic phenomenon. Because this desire to use supersedes all else, people neglect their physical and behavioral health needs. They also often lose their jobs, families, and homes before they seek treatment. As a result, when people do seek care, they often have multiple untreated medical and behavioral health problems. This leads to increased care needs and requires the OTP to closely coordinate with other health care providers, or to provide medical and behavioral health care onsite. They are not funded to provide these services or care coordination.

Current financing needs and gaps specific to OTP settings

Before behavioral health integration into Washington Apple Health (Medicaid), OTPs were paid a daily rate. This rate has not increased in years for Apple Health fee-for-service (FFS) patients, despite continued increases in the costs of delivering services. Increases in costs for services, costs for staffing, and the medical needs of persons seeking services in the OTPs have also increased, creating funding gaps. Because of the shortage of SUD professionals, as well as other behavioral health support staff, OTPs cannot match the competitive salaries offered in the private sector.

With integration, each OTP has separate arrangements with each MCO about how they are paid and what services they are paid for. This leads to an inability to determine a baseline cost in today's dollars for the required services OTPs provide. On the FFS side, the all-inclusive daily bundled rate has not been revised in decades and is also not reflective of the cost in today's dollars of providing care.

The Governor did propose investing $16,850,000 beginning in 2023 to increase access to Food and Drug Administration (FDA)-approved medications through implementation of bundled payments based on current Medicare Part B rates for opioid disorder treatment services. Opioid treatment programs are the only facilities legally able to offer all three medications and the proposed rate increase would hopefully increase the number of providers operating in Washington state offering these medications.

Recommendations

A required set of standardized services

In 2019, as part of a CMS Innovative Accelerator Project, HCA worked with a CMS consultant to develop this set of 15 standards. HCA staff believe that the implementation of these standards will improve the quality of care provided in OTPs and ensure that all patients in all OTPs will have equal access to same set of services.

Standard #1: Stewardship of state resources

All OTPs must have a description of how the agency works with individuals to address the funding of an individual's treatment costs. This includes a mechanism to address changes in the individual's ability to pay.

All OTPs must also screen all uninsured, and self-pay patients for appropriateness for Apple Health and/or Medicare and be able to facilitate these individuals' enrollment into Apple Health and/or Medicare.

Standard #2: FDA-approved OUD medications

All OTPs must offer all three forms of FDA-approved OUD medications: methadone, buprenorphine, and naltrexone products. This includes injectable forms of naltrexone and buprenorphine products.

HCA will work with MCOs to ensure all OTP providers are able to offer the three forms of FDA-approved OUD medications to Apple Health beneficiaries in this treatment setting.

Standard #3: Timing of the medical induction

Medical induction is the term used to describe the process of starting someone on methadone, buprenorphine or naltrexone. In the past, medical inductions at OTPs occurred after a Washington Administrative Code (WAC)-required American Society of Addiction Medicine (ASAM) biopsychosocial assessment. The assessment is complex, lengthy, and has little therapeutic value. It is an administrative requirement that often takes weeks to schedule. Starting with the therapeutic intervention, medical induction before requiring completion of the assessment should be the standard of care.

All OTPs must allow patients to receive a medical induction onto FDA-approved OUD medications first, prior to a patient's completion of the biopsychosocial assessment.

Exemptions can be made, if a medical prescriber is not available at the time of the initial visit to the OTP, and if a patient would prefer to begin their OTP treatment with the completion of the assessment.

Standard #4: Overdose prevention and drug user health

Every person admitted to an OTP will receive a program orientation to overdose prevention and drug user health within two weeks of admission.

The orientation may be conducted by any staff member on the OTP treatment team. This orientation shall be made verbally at the earliest opportunity, when a patient is stable and capable of understanding and retaining the information presented. OTP staff must document that this orientation was completed in the patient's health records.

Orientation to overdose prevention must include the following HCA-mandated curriculum. The OTP shall:

1. Furnish a naloxone kit or a prescription for such a kit from a prescriber.

2. Provide instruction on the kit's use, including, but not limited to, recognizing the signs and symptoms of overdose, calling 911 in overdose situations, and the Washington State Good Samaritan laws.
3. Provide a new naloxone kit or prescription upon a patient's self-reported expiration or use of the old kit. The OTP shall be exempt from this requirement for one year, if a patient refuses a naloxone kit and/or the patient reports already having a naloxone kit.
4. Offer a new naloxone kit yearly during the patient's required annual medical examination noted in WAC 246-341-1020(12).
5. Inform the patient about the location of the nearest syringe service program, relative to the patient's self-reported home.
6. Provide information about services available at a syringe service program and discuss a fact sheet that is developed by HCA and DOH regarding harm reduction.

Standard #5: Interim maintenance

Even in facilities that allow medical inductions before the Washington-required biopsychosocial assessment, staffing limitations limit the number of new patients that can be admitted at a time. To help prevent death among patients waitlisted for treatment, all nonprofit or publicly owned OTPs must have policies and procedures in place on how to request and implement federally allowable OTP interim maintenance procedures from the State Opioid Treatment Authority, DOH, and the federal Substance Abuse and Mental Health Services Administration (SAMHSA).

Interim maintenance treatment temporarily prioritizes new OTP patients to receive medication and medical-related treatment services prior to psychosocial counseling services. When interim maintenance is not in place, baseline medication-related treatment services are required to be offered at the same time as psychosocial counseling services in an OTP setting.

Requirements for interim maintenance treatment include the following.

1. Opioid agonist treatment medications must be administered daily under observation.
2. Unsupervised or "take-home" use is not allowed.
3. An initial treatment plan and periodic treatment plan evaluations are not required.
4. A primary counselor is not required to be assigned to the patient.

Interim maintenance cannot be provided for longer than 120 days to an OTP patient in any 12-month period. Rehabilitative, education, and other counseling services are not required to be provided to the patient during this time.

Provision of interim maintenance requires authorization from the State Opioid Treatment Authority, DOH, and SAMHSA.

Federal law does not allow for-profit OTPs to utilize OTP interim maintenance procedures to prevent patient waitlists, so for-profit OTPs would be exempt from this standard.

See 42 CFR § 8.12 Federal opioid treatment standards for additional information.

Standard #6: Universal guest dosing

Guest dosing means a patient of one OTP may be dosed at another program, if that patient travels to another area. Guest dosing provides a mechanism for OTP patients, who are not eligible under federal

rules for take-home medication, to travel from their home clinic for health care needs, business, pleasure, or family emergencies to continue receiving their medication. It also provides an option for patients, who need to travel for a period that exceeds the amount of eligible take-home doses, to do so within regulatory requirements.

All OTPs must use the same universal guest dosing form and billing policy created by HCA.

All OTPs will bill MCOs and private insurance directly for each insured patient's take-home medication or guest dosing service.

Standard #7: Split dosing of medications

Split dosing means dividing an OTP patient's daily dose, usually taken all at once, into a divided dose taken twice or more a day. Split dosing helps maintain a constant level of medication throughout the day and night. This is particularly important in people who are pregnant. Pregnancy changes the way the body processes medications. This can lead to the dose wearing off before 24 hours, which can lead to the development of cravings and withdrawal symptoms. Splitting the dose reduces the patients' risk of developing opioid withdrawal symptoms or cravings while on these medications.

All OTP medical directors must meet with each patient individually to assess for the patient's appropriateness for split dosing of medications.

No OTPs may have an agencywide policy prohibiting split dosing for all patients.

Standard #8: OTP central registry

All OTPs must use the HCA-funded OTP central registry to coordinate reporting and patient care, and to prevent dual enrollments at OTPs.

Lighthouse Software Systems (Lighthouse) operates a central registry and disaster assistance program for the substance abuse treatment industry. The web-based software application is designed to ease the burden for clinical providers to perform required, multiple enrollment verifications prior to admitting patients. The system also provides a continuum of care in times of emergency for patients receiving treatment for substance abuse.

Standard #9: Emergency planning

All OTPs must have yearly updated emergency plans in place for unexpected program closures and/or operating at a reduced capacity during an emergency.

1. All OTPs must use the HCA-funded Lighthouse OTP central registry in the development of each program's emergency planning procedures.
2. All OTPs must submit their emergency plans to HCA yearly for review.
3. All OTPs emergency plans must contain content requiring the treatment agency to hold enough medication on site to serve the existing patient census and absorb a prospective new patient surge for two weeks in an emergency.

Standard #10: Patient-centered services

All OTP providers who want to offer onsite, co-located, person-centered, holistic services, which are both Apple Health reimbursable and above and beyond the services required by state and federal law, should be able to do so. Examples of these types of services may include, but are not limited to:

1. Level 1 outpatient SUD services.
2. Level 2 intensive outpatient SUD services.
3. SUD peer support services.
4. Supported employment services.
5. Supportive housing services.
6. Mental health non-residential/outpatient level services, including psychosocial and psychiatric services.
7. Physical health services, such as primary care services, including wound care.
8. Physical health services related to the prescription of medications to treat other SUD diagnoses such as, but not limited to, alcohol use disorder.

HCA will work with all MCOs to ensure that OTP providers, who wish to provide these types of services, can do so for Apple Health patients within this treatment setting.

Standard #11: Universal suicide screening

All OTPs must implement universal suicide screening with a validated screening tool chosen by HCA. Screens must be performed at all counseling and medical appointments.

All OTPs must document the use of a standardized suicide assessment tool and standardized safety planning tools to be provided by HCA, if a patient screens positive for suicide concerns during the suicide screen.

Standard #12: Laboratory testing

All OTPs must adhere to HCA policies for presumptive and confirmatory laboratory testing to assess for patient use of both prescribed medications and non-prescribed drugs.

HCA will ensure this policy is referenced and enforced in the Apple Health FFS Substance Use Disorder Billing Guide and Apple Health Integrated Managed Care (IMC) Service Encounter Reporting Instructions (SERI).

HCA will work with all MCOs to ensure that OTP providers, who wish to provide presumptive and confirmatory laboratory testing types of services, can do so for Apple Health patients within this treatment setting. This will allow for testing to assess for patient use of both prescribed medications and non-prescribed drugs.

Standard #13: Infectious disease screening, testing, and treatment

All patients receiving care in an OTP must be offered:

1. Viral hepatitis testing, which may be done onsite or by referral.
2. Human immunodeficiency virus (HIV) testing, which may be done onsite or by referral.
3. Tuberculosis (TB) testing, which may be done onsite or by referral.
4. Syphilis testing, which may be done onsite or by referral.

All OTPs must be able to demonstrate that their treatment/recovery plans for patients include provisions for the prevention, care, and treatment of viral hepatitis, HIV, TB, and syphilis, when present. Prevention, care, and treatment may be done onsite or by referral.

Specifically for HIV, all OTPs must screen patients to determine their HIV exposure risk. For those at high risk, OTPs must offer a referral to a provider, who can provide pre-exposure prophylaxis (PrEP), and/or referral to a PrEP navigator through DOH.

If a screened patient chooses not to have these tests, the provider must have the patient acknowledge in writing that such care was offered, recommended, and declined.

Standard #14: Vaccinations for Hepatitis A and B

All patients receiving care in an OTP must be offered:

1. Immunizations for Hepatitis A.
2. Immunizations for Hepatitis B.

Vaccinations may be done onsite or by referral. If a patient chooses to not receive these vaccinations, the provider must have the patient acknowledge in writing that such care was offered, recommended, and declined.

Standard #15: FDA-approved medications for tobacco use disorder

All OTPs must administer and/or dispense all FDA-approved medications for the treatment of tobacco use disorder. HCA will work with all MCOs to ensure all patients can receive these medications from their OTP provider.

Creating centers of excellence

Opioid use disorder "centers of excellence" (COEs) for patients receiving Medicaid have been developed in several states. While the services offered and requirements to participate differ, all states require COEs to provide care coordination. The care coordination provided must support the client in assuring all their physical and any additional behavioral health needs are met. The COEs are also required to track and report on a variety of outcomes.

Opioid treatment programs in Washington are not currently funded to provide care coordination. They have also not been funded to develop the infrastructure or provide the staffing needed to develop data systems capable of tracking referrals or patient outcomes. If funded and developed in Washington, programs that provided these services would be termed Level 1 COEs.

- HCA recommends that all programs become Level 1 COEs. This would require the receipt of additional funding.

HCA recommends that Washington also develop a Level 2 COE. In addition to care coordination and the active management and tracking of referrals and outcomes, OTPs in Washington that wanted to become a Level 2 COE, would receive support to become "medical homes". This would require that OTPs provide primary care and some additional behavioral health services onsite.

Additional funding about needed to become a Level 1 COE would be needed to hire the staff and equipment necessary to support the addition of these Level 2 services. While these services are Medicaid eligible, the current rates of reimbursement would not be enough to cover the costs of the additional staffing and equipment needed.

Estimating the costs and providing a funding structure

Prior to full integration, each Behavioral Health Organization (BHO) negotiated reimbursement rates directly with the OTPs in their region. Rates varied within and across the BHOs. In addition, how encounters were reported to the BHOs varied by region. Because a daily rate was being paid, individual services, for example, physical exams, urine drug tests, SUD counseling visits were not reported to the BHOs. A single code was used to report any service provided in an OTP. To minimize disruption with the transition of funding to the MCOs, the MCOs were directed to continue the rate and reporting structures the BHOs had put in in place. Managed care organizations were allowed to, and many did, increase the rates individual programs received. For patients funded outside of the MCOs, the FFS rate for OTPs remained unchanged.

The historical lack of detailed reporting for the number and type of services being performed in the OTPs makes calculating a rate that reflects the cost of providing all federally required services impossible. To address this issue, HCA recommends that OTPs use the billing structure established by Medicare. To support the costs in system and staff time required to do this, HCA also recommends that the Medicare fee schedule be adopted. The Medicare payment structure requires the reporting of individual service types and the frequency with which they are delivered to be reported. The rates vary by the intensity and frequency of the services provided. This is more reflective of the care that happens over time for people getting care in OTPs. As they become more stable in their recovery, they are allowed more take-home doses and do not have to visit the facility daily. The current daily rate structure does not change with the intensity or frequency of the current services being provided. Without a way to know exactly what services are being provided at what frequency, performance standards cannot be tracked, and value-based payment models cannot be developed.

The adoption of Medicare payment schedule and billing rules would allow the MCOs and HCA to track what services are being provided when. This would allow for the development of performance metrics and value-based payment methodologies. The increased amount of funding programs would receive through this transition would support this transition and better approximate the cost of providing the services required by federal and state guidance. Appendix A provides a cost analysis performed by Mercer Government Human Services Consulting, reflecting the funding needed to accomplish this change.

Once the type of services being performed are identified and the costs of providing them calculated, analyses that determine the funding needed to support OTPs in becoming Level 1 or Level 2 COEs can be performed.

Waivered health care providers

Federal guidance released in April 2021, Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder, reduced the requirements needed for prescribers to receive a waiver to prescribe buprenorphine products to people experiencing OUD.

Providers may now prescribe buprenorphine for up to 30 patients without formal training or assurance that linkage to counseling and other secondary services will occur. Providers are still required to register and complete a notice of intent to prescribe buprenorphine, an online process through SAMHSA.

These changes will make it much easier for providers in emergency departments, hospitals, skilled nursing facilities, and jails to start or continue people on buprenorphine. This will improve transitions of care and

reduce overdose risk. HCA has already published and given guidance on a billing code that can be used by hospitals for this purpose.

Since the pandemic, fewer prescribers are using their waivers to treat patients with OUD covered by Medicaid. To better understand why providers who have waivers are not using them, HCA will re-survey providers to see what barriers they describe in prescribing buprenorphine to their patients enrolled in Apple Health. HCA will also refresh messaging to providers about the enhanced billing rates, in alignment with Medicare, because several years have passed since the rate change was approved by the Legislature and implemented. New providers may not be aware of this change.

HCA staff will continue to monitor the "Providers: Proportion of active Buprenorphine waivered providers" indicators and summary report on the Healthier Washington Dashboard Opioid Use Disorder (OUD) Treatment for Medicaid Population to track trends. Although a decline in the number of providers using their waiver is concerning, the proportion of Apple Health enrollees starting and receiving buprenorphine out of those who have a diagnosis of OUD has remained the same.

Lowering the costs of drugs used to treat OUD

Opioid replacement therapy with methadone- or buprenorphine-containing products is the most effective treatment for OUD.

Methadone has been off patent for decades and is inexpensive. While the price of buprenorphine oral products has decreased over time, longer-acting buprenorphine products remain quite expensive, because they are new to the market and are more complex formulations. Any new drugs developed are also likely to be expensive.

There is not a ready solution to reduce the costs of prescription drugs that fall into these categories. The demand for medications used to treat OUD is high and increasing. There are no incentives or requirements in place that force the manufacturers or anyone else along the supply chain to lower drug associated costs. Unlike Hepatitis C, there is not a one-drug-fits-all medication that can be used to treat OUD. Therefore, a single-type purchase agreement for a particular formulation of a drug would help some, but not all patients. While several efforts are underway in Washington to determine how the state might reduce prescription drug costs, they will take time and legislation to develop. For prescription drug prices to be effectively lowered, either by individual class of drug or across all drugs, action at the federal level is likely needed.

Conclusion

This report has described the increase in opioid related morbidity and mortality in the state of Washington, largely associated with the introduction of fentanyl into the illicit drug supply. Several years prior to this rise in fentanyl-related overdose deaths, the Legislature asked HCA to:

- Offer a set of recommendations related to the delivery of care in OTPs; and
- Address the need for increased access to services for people with OUD, while controlling costs.

Given the increased potency of fentanyl, the need to use methadone as the most potent opioid replacement therapy is expected to increase. Because OTPs are the only agencies allowed by federal law to treat people experiencing OUD with methadone, this report has become more relevant. The need to provide standardized, high-quality care in OTPs that meets federal and state requirements has never been more important.

To do so, OTPs must adopt and provide a standardized set of services. They must be adequately funded to report and track the type and number of services being provided. Adopting the same fee schedule and billing rules used by Medicare would help to identify the services being provided and the costs associated with doing so. Once a cost basis for the required services delivered in an OTP can be determined, analyses can be done to determine the costs needed to provide Level 1 and Level 2 COE services in OTPs. The number of providers actively using their waivers to prescribe buprenorphine will continue to be monitored, as will opportunities to purchase drugs used to treat OUD at lower costs.

This set of actions will ensure that the residents of Washington state struggling with OUD are able to access effective, high-quality treatment.

Appendix A: state of Washington fiscal analysis of opiate substitution treatment reform

Appendix A contains six pages of a Mercer Government Human Services Consulting fiscal analysis.

To access this appendix, please view it on our website.

If you have difficulty viewing this appendix, contact HCA to receive an electronic copy.